# §170.315(f)(3) Transmission to public health agencies – reportable laboratory tests and value/results

**2015 Edition CCGs**

**Version 1.3 Updated on 06-15-2020**

## Revision History

| Version # | Description of Change | Version Date |
|---|---|---|
| 1.0 | Initial Publication | 10-22-2015 |
| 1.1 | Revised to indicate this certification criterion is in scope for the CEHRT definition. | 12-07-2015 |
| 1.2 | Added hyperlinks for the test tool/data, NIST Normative Test Process Document, and 2015 MU Specification Sheet. | 01-29-2016 |
| 1.3 | Updated the Security requirements per 21st Century Cures Act. | 06-15-2020 |

## Regulation Text

**Regulation Text**

§170.315 (f)(3) *Transmission to public health agencies – reportable laboratory tests and value/results—*

Create reportable laboratory tests and values/results for electronic transmission in accordance with:

(i) The standard (and applicable implementation specifications) specified in §170.205(g).

(ii) At a minimum, the versions of the standards specified in §170.207(a)(3) and (c)(2).

## Standard(s) Referenced

### Paragraph (f)(3)(i)

§ 170.205(g) *Electronic transmission of lab results to public health agencies*. HL7 2.5.1. *Implementation specifications*. HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) with Errata and Clarifications and ELR 2.5.1 Clarification Document for EHR Technology Certification

**Paragraph (f)(3)(ii)**

§ 170.207(a)(3) International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) International Release July 2012 and US Extension to SNOMED CT® March 2012 Release

§ 170.207(c)(2) Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40, Released July 2012, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc.

# Certification Companion Guide: Transmission to public health agencies – reportable laboratory tests and value/results

This Certification Companion Guide (CCG) is an informative document designed to assist with health IT product development. The CCG is not a substitute for the 2015 Edition final regulation. It extracts key portions of the rule's preamble and includes subsequent clarifying interpretations. To access the full context of regulatory intent please consult the 2015 Edition final rule or other included regulatory reference. The CCG is for public use and should not be sold or redistributed.

Link to Final Rule Preamble

| Edition Comparision | Gap Certification Eligible | Base EHR Definition | In Scope for CEHRT Definition |
|---|---|---|---|
| Unchanged | No | Not Included | Yes |

## Certification Requirements

Privacy and Security: This certification criterion was adopted at § 170.315(f)(3). As a result, an ONC-ACB must ensure that a product presented for certification to a § 170.315(f) "paragraph (f)" criterion includes the privacy and security criteria (adopted in § 170.315(d)) within the overall scope of the certificate issued to the product.

- The privacy and security criteria (adopted in § 170.315(d)) do not need to be explicitly tested with this specific paragraph (f) criterion unless it is the only criterion for which certification is requested.

- As a general rule, a product presented for certification only needs to be tested once to each applicable privacy and security criterion (adopted in § 170.315(d)) so long as the health IT developer attests that such privacy and security capabilities apply to the full scope of capabilities included in the requested certification.
- However, exceptions exist for § 170.315(e)(1) "VDT" and (e)(2) "secure messaging," which are explicitly stated.
- § 170.315(d)(2)(i)(C) is not required if the scope of the Health IT Module does not have end-user device encryption features.

**Table for Privacy and Security**

- If choosing Approach 1:
  - Authentication, access control, and authorization (§ 170.315(d)(1))
  - Auditable events and tamper-resistance (§ 170.315(d)(2))
  - Audit reports (§ 170.315(d)(3))
  - End-user device encryption (§ 170.315(d)(7))
  - Encrypt authentication credentials (§ 170.315(d)(12))
  - Multi-factor authentication (MFA) (§ 170.315(d)(13))
- If choosing Approach 2:
  - For each applicable P&S certification criterion not certified for Approach 1, the health IT developer may certify using system documentation which is sufficiently detailed to enable integration such that the Health IT Module has implemented service interfaces the Health IT Module to access external services necessary to meet the requirements of the P&S certification criterion. Please see the *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* Final Rule at 85 FR 25710 for additional clarification.

Design and Performance: The following design and performance certification criteria (adopted in § 170.315(g)) must also be certified in order for the product to be certified.

- When a single quality management system (QMS) is used, the QMS only needs to be identified once. Otherwise, the QMS' need to be identified for every capability to which it was applied.
- When a single accessibility-centered design standard is used, the standard only needs to be identified once. Otherwise, the accessibility- centered design standards need to be identified for every capability to which they were applied; or, alternatively the developer must state that no accessibility-centered design was used.

**Table for Design and Performance**

- Quality management system (§ 170.315(g)(4))
- Accessibility-centered design (§ 170.315(g)(5))

## Technical Explanations and Clarifications

**Applies to entire criterion**

***Clarifications:***

- For the public health certification criteria in § 170.315(f), health IT will only need to be certified to those criteria that are required to meet the measures the provider intends to report on to meet Objective 8: Public Health and Clinical Data Registry Reporting.
- This certification criterion is intended for technology used in the inpatient (including emergency departments) setting.
- There is no transport standard required for this criterion. [see also 77 FR 54247]
- The NIST Electronic Laboratory Reporting (ELR) Test Tool tests conformance to the requirements in HL7 Version 2.5.1 Implementation Guide (IG): Electronic Laboratory Reporting to Public Health, Release 1 with Errata and Clarifications, and ELR 2.5.1 Clarification Document for EHR Technology Certification. In the Implementation Guide, RE means "Required, but may be empty" and is not an optional requirement. That is, an RE element is required to be implemented in the EHR technology, but operationally the data may or may not be present (depending on business rules and data availability). The Alternate and non-Alternate data elements have been specified as RE in the IG to ensure the technology can support (receive, process, store, send, etc.) both types (whether or not a particular installation site utilizes/needs this capability is irrelevant for certification testing, which is focused on making sure that buyers of certified EHR technology have the capability). Any Text for Patients and Provider are also RE, and therefore not optional for certification. With regard to repeatable fields, Patient Name (PID.5) can have unlimited repeated instances, and the IG indicates that supporting repeatable fields is a requirement. To support this requirement, the ELR Test Tool and Test Data ensure certified technology can support a minimum of two instances of PID.5.
- The CDC has published the Reportable Condition Mapping Table (RCMT) that provides a subset of LOINC® and SNOMED CT® codes associated with reportable conditions. RCMT can be obtained from CDC vocabulary server PHIN VADS (*http://phinvads.cdc.gov*). [see also 77 FR 54247]
- LOINC® SDO has created a tool known as "RELMA," which helps to map the local tests to standard LOINC® laboratory tests. LOINC® SDO provides RELMA training twice a year and, through a partnership with LOINC® SDO, the CDC provides RELMA training to the public health community at least twice a year with a special focus on microbiology lab tests. [see also 77 FR 54247]

### Paragraph (f)(3)(i)

Technical outcome – The Health IT Module can electronically create reportable laboratory tests and values/results messages which can be transmitted to public health agencies according to the HL7 2.5.1 standard, HL7 Version 2.5.1 Implementation Guide for Electronic Laboratory Reporting to Public Health, Release 1 with Errata and Clarifications, and ELR 2.5.1 Clarification Document for EHR Technology Certification.

#### *Clarifications:*

- No additional clarifications available.

### Paragraph (f)(3)(ii)

Technical outcome – The Health IT can represent data in the reportable laboratory test message using, at a minimum, the July 31, 2012 International Release of SNOMED CT® with the March 2012 Release of the US Extension to SNOMED CT® and Version 2.40 of LOINC®.

#### *Clarifications:*

- We provide the following OIDs to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards.

- § SNOMED CT® OID: 2.16.840.1.113883.6.96
- § LOINC® OID: 2.16.840.1.113883.6.1 [see also 80 FR 62612]

- Health IT Modules can present for certification to a more recent version of SNOMED CT® (than the July 31, 2012 International Release and the March 2012 Release of the US Edition) and LOINC® (than Version 2.40) per ONC's policy that permits certification to a more recent version of certain vocabulary standards. [see also 77 FR 54269]

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